REMARKS

The Office Action dated May 17, 2006, has been carefully considered. Claims 1, 4, 33, 35, and 42 have been amended. The amendments are supported throughout the specification, for example at page 17, lines 17-21. Claims 1, 4, 5, 7-33, 35, 36, 38-42 and 47 are in this application.

35 U.S.C. § 102

Claims 1, 4, 5, 7, 8, 10, 13-18, 20, 21, 27, 29, 30, 32, 35, 36, 38-42 and 47 are rejected under 35 U.S.C. § 102(e) as being anticipated by US 2003/0027833.

Cleary et al. disclose, in a first embodiment, a pharmaceutical composition for topical administration of a local anesthetic agent. The composition can be in the form of a gel or a liquid that, upon application to the body surface, forms a film (para. 0014-0015).

In contrast to Cleary et al., the invention defined by the present claims discloses a patch that is already a film before application to the body for use. As amended, the claim language recites that the present invention is a film when applied to the body, and, as such, is applied to the body by wetting with water to cause the film to become tacky so as to stick to the body. Since Cleary et al. does not teach such a film that is applied to the skin, Cleary et al. does not anticipate the claims.

Cleary et al. teach a second embodiment that they term a "drug delivery system" (para. 0088). The drug delivery system comprises more than one layer which includes a drug reservoir layer with another layer laminated to the drug reservoir layer. The description of this embodiment is clear and precise at para. 0023: "The system is a device in the form of a laminated composite". The fact that the system is termed a "device" provides the first indication that it is something of permanence. As the Examiner pointed out, this paragraph states that the device has an "optional" upper backing layer laminated to the drug layer, but the statement that the system is a *device in the form of a laminated composite* indicates that while the upper backing layer may be optional, there is a composite of some kind intended by this embodiment. Indeed, in paragraph 0024, it is explained that when the upper backing layer is absent, a hydrophobic layer substitutes to serve the same purpose. Yet another alternative is explained in

the section headed by the title "Drug Delivery Systems" starting at para. 0088. In this section, the system is described as containing the drug reservoir layer in combination with either an upper backing laminate, serving as a skin or, alternatively, the drug reservoir layer has a conventional bioadhesive laminated thereto.

The drug delivery system is also explained at paragraph 0091. Here, it is explained that the drug delivery system can have the drug reservoir layer in the form of a mixture with the bioadhesive material and that, in such a case, a single layer serves as both the drug reservoir and the bioadhesive. Reading this statement with knowledge that the drug delivery system is described as "a device in the form of a laminated composite" (para. 0023), this "monolithic" layer must be used in combination with the upper backing layer laminated to the upper surface of the drug delivery-bioadhesive layer. Indeed, this interpretation of the description at para. 0091 is made explicit in the recital at claims 50 and 51.

Thus, it is clear that the drug delivery system has more than just the drug delivery layer, whether the additional layer is an upper backing or a lower bioadhesive layer. In any case, this embodiment does not consist of a single polymeric layer, and does not dissolve or disintegrate when washed with water for removal from the skin, as recited in the presently claimed invention.

Thus, whether alluding to the liquid/gel embodiment or the solid drug delivery system taught by Cleary et al., neither of these embodiments fulfill all the requirements of the claimed invention. For this reason Cleary et al. does not anticipate the claims.

The Examiner also relied on the drug delivery system of Cleary et al. in another respect. The drug delivery system was relied upon for its teaching, at paragraph 0091, of a drug reservoir layer that can be a bioadhesive material (Off. Act. p. 5, last para.), arguing that, in that respect, it is inherent that the polymer will become tacky upon wetting the skin. Applicant disagrees with this rationale. There are many ways in which a material can be bioadhesive without becoming tacky upon wetting; for example, as in the bioadhesives taught in U.S. Pat. 7,076,282. In light of the fact that Cleary et al. does not provide any teaching that the bioadhesive material is so constructed as to become tacky upon wetting, and in light of the fact that bioadhesives are not always materials that become tacky upon wetting, it is improper to rely on this theory of inherency as grounds for the rejection (see MPEP 2112). Thus, the Examiner has not provided

support that Cleary et al. teach the limitation of the claims that the polymer matrix layer becomes tacky upon wetting.

The Examiner also relied on the teaching in Cleary et al. at paragraph 0060 as disclosing that the active agent is encapsulated in liposomes, further arguing that liposomes can form nanospheres or microspheres. Cleary et al. do not disclose that the active agent is encapsulated in liposomes. Actually, Cleary et al. teach that the presence of liposomes in their formulation is counterproductive to their purpose, and they specifically call attention to the fact that the invention contemplates a non-liposomal carrier, for that reason. They merely explain that if a low level of liposomes is in the carrier composition it will not preclude the composition from being used so long as the level is low enough that "the composition is substantially free of liposomes per se." This mention of liposomes does not include a statement that their active agent is encapsulated in liposomes and, in light of the context in which liposomes are discussed, the Examiner has no rationale basis to argue that Cleary et al. teach that in their compositions the active agents are encapsulated in liposomes nor that this meets the required limitation of claim 16 that the active agent be encapsulated in nanospheres or microspheres.

For all the above reasons, Applicant respectfully maintains that Cleary et al. do not anticipate the claimed invention.

35 U.S.C. § 103

Claims 9, 11, 12, 19, 22-26, 31, 33, 35, and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over any of US'833 in view of US 2001/0007671 ('671).

US'833 was discussed above and that discussion is incorporated herein. US'833 does not teach the following limitations of the claims:

- the patch is configured as a film when applied to the body, and is applied to the body by wetting with water to cause the film to become tacky so as to stick to the body
- the patch consists of a single polymeric layer
- the patch dissolves or disintegrates when washed with water for removal from the skin

The Examiner relied on US'671 for the teaching that the skin can be wetted before application of the patch. However this does not overcome the defect. The claimed limitation

recites that the patch is wetted and this causes the film to become tacky for adhering the patch to the body. US'671 does not disclose a composition that becomes tacky upon being moistened nor that moistening causes it to adhere to the body. Thus the combined teachings do not cure the defect.

Furthermore US'833 teaches away from the object of the present invention in teaching that, preferably, the patch does not disintegrate when it is removed from the skin (para. 0015). This teaching would lead one to configure a patch using that combination of teachings of the two references that would not result in the claimed invention. This teaching would also remove any suggestion or motivation for success of any combination that would result in the present invention, which dissolves or disintegrates for removal from the skin.

In light of the teaching away from the invention and the fact that US'833 does not teach the above-listed limitations and US '671 does not teach these limitations either, the combination of the teachings of the two references would still not lead one to the invention as claimed. Therefore, the claims are patentable over this combination of references.

Claims 9, 11, 12, 22-26, 28, 31, 33, 35, and 36 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US'833 in view of US 6,419,935 ('935).

US'833 does not teach the limitations listed in the section above. The Examiner relied on US'935, not for the '935 teaching of components of its polymeric matrix and reinforcing member, but solely for the teachings enumerated by the Examiner (Examiner's rationale at page 11, last paragraph et seq.). The enumerated teachings relied upon include the teaching that wetting the skin before applying the polymeric patch leads to easier manipulation during application and removal. While wetting the skin may make the US '935 invention easier to manipulate, nothing in the US'833 teachings indicates that wetting makes that invention easier to manipulate. Thus the Examiner has not provided a combination of teachings that cures the defect of US'833, specifically, lack of any suggestion for inventing a patch that is configured as a film when applied to the body, and is applied to the body by wetting with water to cause the film to become tacky so as to stick to the body.

Further, The Examiner relied on US'935 for the teaching of the size and thickness of the patch as claimed as well as shapes designed to fit on various parts of the body. However, the

teaching of the same size for a patch does not cure the defects of US'833. Specifically the "drug delivery system" (para. 0088) is nonetheless not a single polymeric layer, since it is composed of a drug reservoir layer combined with a laminate layer. Further it is not a patch that dissolves or disintegrates when washed with water, since the laminate does not dissolve or disintegrate. Thus, even if the "drug delivery system" is the claimed size, it does not meet all the limitations of the claimed invention. Last, even if US'935 can be prepared as a particular thickness, as recited in the claimed invention, the Examiner hasn't shown that the one skilled in the art could make the invention of US'833 to the same thickness. Thus the combination of the references does not cure all the defects.

In light of the fact that US'833 does not teach the limitations listed in the section above and the enumerated teachings of US '935 that the Examiner relied on does not teach these limitations either or has not been shown to be applicable to the US '833 component ingredients, the combination of the teachings of the two references would still not lead one to the invention as claimed. Therefore, the claims are patentable over this combination of references.

Claim 28 was rejected under 35 U.S.C. § 103(a) as being unpatentable over any of US'833.

In light of the fact that US'833 does not teach the limitations listed in the first section directed to the obviousness rejections and no cure for that defect has been argued, the Examiner's new rationale does not overcome the existing defects. Since the cited prior art does not suggest an invention having all the limitations of the claimed invention, the claimed invention is not obvious.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required.

Serial No. 10/091,935 Docket No. 4686-110 US

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: November 6, 2006

Cynthia Soumoff, Ph.D., J.D.
Reg. No. 38,314
Attorney for Applicant

MATHEWS, SHEPHERD, McKAY & BRUNEAU, P.A.
29 Thanet Road, Suite 201
Princeton, NJ 08540
Tel: 609 924 8555
Fax: 609 924 3036